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10/578,573	01/19/2007	Patrick Sadok	71247-0058	1836

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EXAMINER

MATTER, KRISTEN CLARETTE

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3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,573	Applicant(s) SADOK ET AL.	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract is just one long run-on sentence that includes claim language such as "comprising." In addition, reference to any Figures should be removed from the abstract. Correction is required. See MPEP § 608.01(b).

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.

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(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Applicant is strongly encouraged to add appropriate headers where necessary.

Drawings

The drawings are objected to because of the unlabeled rectangular box(es) shown in figure 2. The drawings should be provided with suitable descriptive legends or words within the boxes themselves. See: 37 CFR 1.84 (n) and (o).

37 CFR 1.84(n) and (o) permit use of symbols which are not universally recognized, subject to approval by the Office, if they are not likely to be confused with existing conventional symbols, and if they are readily identifiable. In addition, **suitable descriptive legends may be used subject to approval by the Office, or may be required by the examiner where necessary for understanding of the drawing.** (Emphasis added). Thus the examiner may require, on a case-by-case basis, the use of descriptive legends where it is believed that such will facilitate a clear understanding of the drawings without undue reliance on the specification for understanding of the subject matter depicted therein. "When possible, a drawing should be so complete that the purpose and operation of the invention may be readily understood by one

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skilled in the art by means of a mere inspection of said drawing. The necessity of reading the specification in connection with the drawing should be avoided, if possible." See *Ex Parte Hartley*, 1901 C.D. 247 (Comm'r Pat. 1901).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim(s) are replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device.

Some *examples* of indefinite language in the claims include the following:

In claim 1, lines 8-10, “the biological segments” and “the mechanical segments” lack antecedent basis since only one biological segment and one mechanical segment are required to read on the claim (i.e., “the mechanical segments” should be changed to --the at least one mechanical segment--).

In claim 1, line 13, “their inputs” lack antecedent basis.

In claim 1, line 14, “movement and position acquisition resources” is confusing because these elements were previously claimed as “Resources for acquiring movements” and “resources for acquiring the spatial position” making it unclear if these are in fact the same elements.

Applicant is encouraged to keep claim language consistent for all claimed elements.

In claim 1, lines 17-18, the movement intentions” lack antecedent basis.

In claim 1, line 19, “at least one biological segment” is confusing because a biological segment has already been claimed so it is unclear if this is the same or different element.

In claim 1, line 21, “these segments” lack antecedent basis since only one biological segment is required for the claim.

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In claim 1, lines 23-24, “the field of activities” and “the configuration” lack antecedent basis.

In claim 1, line 25, “said parameters” is confusing because there are several parameters claimed (i.e., control and applicable to the configuration) making it unclear which parameters are being referred to here.

In claim 1, lines 25-26, “the information” lacks antecedent basis.

In claim 1, lines 26-27, “resources for acquiring movements or movement intensions” is confusing because it is unclear which resources are actually being referred to here.

In claim 1, line 29, “control resources” is confusing because there are already control resources claimed, making it unclear if this is the same element or a different one.

In claim 4, lines 2-3, “each mechanical articulation connecting two mechanical segments” is confusing because claim 1 doesn’t require the mechanical articulations to connect several mechanical segments (i.e., only at least one mechanical segment connected to the reference structure is claimed).

In claim 4, line 5, “its position” is confusing because it is not clear which element “its” is referring to (i.e., pronouns should be replaced with the name of the element actually being referred to).

In claim 4, lines 6-7, “the biological articulation” lacks antecedent basis.

In claim 4, line 11, “the mechanical articulation corresponding to the articulation of the shoulder” lacks antecedent basis.

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In claim 6, line 2, “each articulation of a mechanical segment” is confusing because as discussed above, only one mechanical articulation is claimed. Applicant is also reminded to keep claim language consistent when referring to specific elements.

In claim 6, line 3, “a biological articulation” has already been referred to in claim 4, making it unclear if this is the same or different articulation.

In claim 8, lines 3-4, “the slide of the biological axis of rotation” lacks antecedent basis.

In claim 9, line 5, “these being driven” is confusing because it is unclear what element “these” is referring to.

In claim 9, line 6, “a biological segment” is confusing because --at least one biological segment-- was previously claimed, so if there is more than one biological segment, it is unclear which is being referred to.

In claim 10, line 2, “the fixed part and the mobile part” is confusing because these elements are not actually required to read on the claims (i.e., there can be resources for measuring neuro-muscular stimuli instead).

In claim 10, line 4, “a biological segment” is confusing because --at least one biological segment-- was previously claimed, so if there is more than one biological segment, it is unclear which is being referred to.

In claim 13, line 3, “the articulated mechanical segments” lack antecedent basis. Applicant is again encouraged to keep language consistent for each claimed element.

In claim 15, line 3, the phrase “in particular” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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In claim 16, line 2, “at least one mechanical segment” is confusing because there is already at least one mechanical segment claimed, making it unclear if this the same element or a different one.

In claim 17, line 2, “it includes” is confusing because it is unclear which element “it” is referring to. Also, applicant is encouraged to keep claim language consistent with "the control, acquisition and activation resources" in lines 2-3.

In claim 17, line 4, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 20, line 2, “a mechanical segment” is confusing because there is already at least one mechanical segment claimed, making it unclear if these are the same element or a different element from those already claimed.

Please note that the above are merely examples of indefinite claim language in the claims and is not meant to cover every 112 issue. Applicant is encouraged to carefully re-read all the claims to correct any similar mistakes not specifically mentioned by the examiner.

Claim Rejections - 35 USC § 102 /35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9, and 12-19, as best understood by the examiner, are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McBean et al. (US 7,396,337, herein referred to as “McBean”).

Regarding claim 1, McBean discloses an exoskeletal system providing assistance in terms of support and motor-power for at least one biological segment of a person (abstract), where the system has: an exoskeletal weight-bearing structure (14 and the rest of the frame) with resources (12) for adaptation onto the person, and composed of a reference structure (i.e., 122 or the top frame segments on the upper arm for example; since the device is able to determine position, there must be some sort of reference structure) and at least one mechanical segment (i.e., lower part of frame 14 on the lower arm for example) connected to the reference structure by a mechanical articulation (24); resources (32) for acquiring the movements of the biological segments; resources (24) for acquiring the spatial position of the mechanical segments in relation to the reference structure; operating resources (36) for providing motor-power to the articulated mechanical segments; and control resources (34) connected at their inputs to the movement and position acquisition resources (column 7, lines 1-10) and at their outputs to the operating

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resources in order to control them (column 7, lines 5-25); characterized in that: the said resources for acquiring movements also acquire movement intentions (column 8, lines 1-7) and are composed of resources for time related measurement of the effort (i.e., the sensor can measure velocity which is time related measurement) coming from the at least one biological segment and time-dependent resources for detecting directions of the movements (i.e., the sensors determined joint angle and other positional information that relates to direction), the said control resources include: control parameters (column 7, lines 10-25) applicable to the person and the field of activities, and parameters applicable to the configuration of the exoskeleton (i.e., the device would inherently be configured for a certain type of movement depending on which joint is being helped), processing resources (microchips of 34), that proportionally determine characteristics relating to speed, acceleration, deceleration, and effort of the operating resources in order to properly control movement of the exoskeleton (column 3, lines 15-20), and control resources (outputs of 34) used to control the operating resources as determined by the processing resources (microchips of 34).

To the extent, if any, that the system doesn't specifically mention a "reference structure" examiner contends that including a reference structure would have been obvious to one of ordinary skill in the art depending on the particular utility of the device (i.e., which joints are being treated, must be immobilized, etc.) since such structures are well known and commonly used in the art when determining parameters such as position in exoskeletons. In addition, which exact characteristics of the movements are determined by McBean is considered an obvious design consideration to one of ordinary skill in the art depending on the type of condition being treated. There is nothing structurally in McBean limiting the movements being determined and

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controlled by any well known method and it appears as though McBean would perform equally well with any well known means of determining motions and positions.

Regarding claim 2, as discussed above, the device would inherently include algorithms correlating to the biological and pathological characteristics of the person using the device (i.e., controls for knees are different from controls of wrists) in order to determine appropriate amplification, attenuation, and removal of movements (column 2, lines 20-30).

Regarding claim 3, coefficients also seem to be an inherent part of generating "proportional signals" in exoskeleton device. However, to the extent that McBean doesn't explicitly mention a "coefficient," examiner maintains that use of coefficients is well known and common practice in the art and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used coefficients for limiting the amplitude of the person's movements to provide an appropriate proportional movement of the device without injuring the patient.

Regarding claim 9, McBean discloses resource (EMG sensors) for measuring the neuromuscular stimuli sent by the person to his or her muscles.

Regarding claim 12, McBean discloses that the operating resources can be composed of pneumatic muscles of linear pneumatic actuators (column 8, lines 30-50).

Regarding claim 13, McBean discloses that the weight-bearing structure can include adjustable end-stops for limiting the amplitude of movement of the mechanical segments (column 5, lines 25-30).

Regarding claim 14, McBean discloses programmed resources in the control resources (column 7, lines 15-20).

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Regarding claim 15, the control resources are connected to input-output interfaces to control operation of the system else the device would not work (i.e., the sensors send info to the controller that processes that info and controls the exoskeleton accordingly).

Regarding claim 16, the mechanical segment or reference structure is fitted with mounting resources (30 for example) for mounting additional structural structures.

Regarding claim 17, McBean discloses a battery (38) for supplying power to the device.

Regarding claim 18, McBean discloses that the structure can provide assistance to a limb (see Figure 1).

Regarding claim 19, McBean discloses that several devices can be used (column 9, lines 64-67) and on any jointed body part (column 4, lines 50-55). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the device on the trunk/pelvis depending on the presented condition of the patient.

Claims 4-8, 10, and 20, as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as obvious over McBean, as applied to claims 1-3, 9, and 12-19 above, and further in view of Zemlyakov et al. (US 2003/0115954, herein referred to as “Zemlyakov”).

Regarding claim 4, McBean discloses several devices can be used and their positions adjusted with respect to a reference structure as discussed above and that any joint can be assisted. However, McLeod does not specifically mention the shoulder of that the articulation has four degrees of freedom implemented by two pivot links and a radially sliding pivot link. However, Zemlyakov discloses another exoskeleton with a shoulder articulation device (420) having two pivot links (see Figure 7, those corresponding to counterweights 447 and 448) and a

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sliding pivot link (445). Although Zemlyakov only discloses three degrees of freedom, adding an additional or translational degree of freedom is considered an obvious design consideration to one of ordinary skill in the art in order to allow more natural movement of the shoulder which is known to have four degrees of freedom. There is nothing structurally in McBean or Zemlyakov preventing the addition of a fourth degree of freedom and it appears as though the modified McBean device would work equally well with the shoulder having four degrees of freedom. Furthermore, as currently worded, it appears that an additional degree of freedom anywhere on the exoskeleton of the arm would be sufficient to read on the claim language "the mechanical articulation corresponding to articulation of the shoulder" since the claims appear to indicate that several joints correspond to one mechanical articulation.

Regarding claim 5, the pivot links can be considered to be shafted guidance systems (see Figure 7).

Regarding claim 6, depending on the number of and specific joints being treated with the device, it would have been obvious to have at least three degrees of freedom (i.e., a wrist for example since it naturally has at least three degrees of freedom). Zemlyakov teaches both shaftless and shafted guidance systems (see Figure 3), the exact use of which again depends on the movements desired to be produced by the device.

Regarding claim 7, Zemlyakov discloses a circular rail system (445) providing guidance for one mobile slide (452).

Regarding claim 8, the sliding pivot link of Zemlyakov is composed of several successive axes of rotation (see Figure 7) to allow reproduction of a trajectory close to that of the shoulder.

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Regarding claim 10, Zemlyakov discloses concentric restraints (444) but is silent as to a “mobile part” specifically. However, cuffs that allow insertion of a limb by opening are well known and commonly used in the art and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a mobile part in the cuff of Zemlyakov in order to allow a user to more easily insert their limb and to allow better adjustment to different sizes of limbs.

Regarding claim 20, depending on the number of and specific joints being treated with the device, it would have been obvious to have at least three degrees of freedom (i.e., a wrist for example since it naturally has at least three degrees of freedom). Zemlyakov teaches both shaftless and shafted guidance systems (see Figure 3), the exact use of which again depends on the movements desired to be produced by the device.

Claim 11, as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as obvious over McBean and Zemlyakov , as applied to claims 4-8, 10, and 20 above, and further in view of Bonutti et al. (US 5,848,979, herein referred to as “Bonutti”). Zemlyakov lacks an adaptable membrane. However, cushions are well known in cuffs. In addition, Bonutti discloses an arm brace with concentric cuffs having an adaptable membrane (123) in contact with the limb and adapted to the morphology of the limb. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added a membrane/cushion to the modified McBean device in order to increase comfort of the user or to accommodate different sizes of limbs.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2008/0125342 (paragraph [0012] is cited to show that it is well known that the shoulder has four degrees of freedom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771